K131013

510(k) Summary

510(K) Owner:	Nova Biomedical Corporation
Address:	200 Prospect St. Waltham, MA 02454
Phone:	781-894-0800
Fax Number:	784-891-4806
Registration Number:	1219029
Contact Person:	Paul W. MacDonald
Date Prepared:	**01 April 2013**
Proprietary Name:	FOCUS Blood Glucose Monitoring System FOCUS Pro Blood Glucose Monitoring System
Common Or Usual Name:	Glucose Test System (Glucose Meter, Test Strips, and Glucose Controls)
Classification Name:	Glucose Dehydrogenase, Glucose
Device Classification:	II
Regulation Number:	21 CFR § 862.1345
Product Codes:	NBW, LFR, JJX
Predicate Device(s):	K122435: Nova Biomedical Corporation Nova One Glucose Monitor System
Intended Use:	The FOCUS Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or forearm. Intended to be used by a single patient and should not be shared. Intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. Alternative site testing on the forearm can be used only during steady-state blood glucose conditions. Not intended for the diagnosis of or screening for diabetes, and not intended for use on neonates. FOCUS Blood Glucose Test Strips are used only with FOCUS Meters to quantitatively measure whole blood glucose in fresh, human capillary whole blood taken from the fingertip or forearm. FOCUS Control Solution is for use with FOCUS and FOCUS PRO Meters and Test Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

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The FOCUS PRO Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in venous and arterial whole blood and in fresh capillary whole blood obtained from the fingertip or forearm. Intended for testing outside the body (in vitro diagnostic use) for multi-patient use in a professional healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with sing-use, auto-disabling lancing devices. Alternative site testing on the forearm should be used only during steady-state blood glucose conditions. Not intended for the diagnosis of or screening for diabetes, and not intended for use on neonates.

FOCUS PRO Blood Glucose Test Strips are used only with FOCUS PRO Meters for the quantitative measurement of glucose in venous and arterial whole blood and in fresh capillary whole blood taken from the fingertip or forearm.

FOCUS Control Solution is for use with FOCUS and FOCUS PRO Meters and Test Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

Device Description:

The FOCUS and FOCUS Pro Blood Glucose Monitoring Systems are comprised of glucose reagent test strips using glucose dehydrogenase flavin-adenine dinucleotide chemistry (GDH-FAD), a portable hand-held electronic meter and glucose control solutions.

The FOCUS and FOCUS Pro Blood Glucose Monitoring Systems are identical and include identical components (test strips, meter, control solutions), differing only in name to identify the intended user of the system. The FOCUS Blood Glucose Monitoring System is intended for single-patient use (self-testing) and the FOCUS Pro Blood Glucose Monitoring System is intended for multi-patient use (healthcare professional user).

When a user inserts a test strip into the meter, the meter turns on. While the test strip is in the meter, the user obtains a blood or glucose control sample, and then applies the sample to the test strip by touching the test strip to the sample. When an adequate amount of sample has been applied to the test strip, the meter emits an audible beep (when this feature is selected by the user) and the test begins. The meter's liquid crystal display (LCD) shows a test is in process by counting down from the number 4. When the test is complete, the meter displays the glucose result. Blood glucose results are plasma-calibrated to facilitate comparison to standard laboratory methods of blood glucose measurement.

The Blood Glucose Meter is a handheld device powered by one 3-volt non-rechargeable lithium battery. The meter includes a Test Port for insertion of a single test strip, an LCD display, a test strip release button, and buttons to navigate through menu choices. Meter operation is self-prompting using three user interface buttons. In addition to measuring glucose, the Meter also stores blood glucose and control solution results. The Meter offers audible feedback for user inputs, and audible and/or visual feedback for prompts and user alerts. A "battery low" warning alerts the user to change the batteries. Battery charge information is available on the "Meter status screen". The user can select the auto shutoff option to conserve power when the Meter is not in use. Test data and Meter setup information will be stored in a non-volatile form to prevent data loss.

Meter Power Supply: The meter uses single volt (3V) lithium, non re-chargeable battery (# CR2032). Theoretical battery life is approximately 1 year or 1000 tests, when testing is performed three times per day.

No-Coding System. The user is not required to enter a test strip lot-specific Calibration Code into the meter by pressing a button or by inserting a Code Key. FOCUS and FOCUS Pro test strips are assigned only one code and this single code is used for all strip lots.

Glucose Control Solutions are aqueous assayed solutions, containing buffered D-Glucose, viscosity-adjusting agent, preservatives and other non-reactive ingredients (dye). They contain no products of human origin. There are three levels of controls, (Levels 1, 2 and 3).

When a control solution sample is applied to the FOCUS or FOCUS Pro test strip, the meter automatically detects and identifies the glucose control sample using an impedance measurement while performing the glucose measurement. After identifying the sample as control solution, the meter marks the result with the control solution icon and stores the marked result in the meter memory. All control results are excluded from the glucose patient result average calculations.

Summary of the Technological Characteristics:

The FOCUS and FOCUS Pro Blood Glucose Monitors have the same fundamental scientific technology and the same intended use as the predicate Nova One Glucose Monitor System (K122435).

The FOCUS and FOCUS Pro Blood Glucose Monitors measure glucose electrochemically as described in the Nova One Glucose Monitor System (K122435). In the same manner, the magnitude of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in whole blood and control solutions.

Comparison to Predicate Devices:

The FOCUS and FOCUS Pro Blood Glucose Monitors use the same fundamental scientific technology and have the same intended use as the predicate Nova One Glucose Monitor System (K122435).

Performance Studies:

The performance of the FOCUS and FOCUS Pro Blood Glucose Monitors was studied in the laboratory and in Human Factors testing by healthcare professionals and lay users. The studies demonstrated that lay users can obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurements.

Conclusion:

Results of laboratory and Human Factors testing demonstrate that the performance of the FOCUS and FOCUS Pro Blood Glucose Monitors have the same intended uses, with similar technological characteristics and can produce results that are substantially equivalent to results obtained on the predicate devices. The systems perform as intended and raise no new safety or effectiveness issues.

Table 0-1: Comparison of Proposed Devices and Predicate devices

CHARACTERISTIC	FOCUS Blood Glucose Monitoring System (Self-Monitoring)	FOCUS PRO Blood Glucose Monitoring System (Professional Monitoring)	Predicate Device K122435: Nova One System (Professional Monitoring)
Measurement Range (mg/dL)	20 - 600	20 - 600	20 - 600
Operating Principle	Coulometric Electrochemical Sensor	Coulometric Electrochemical Sensor	Coulometric Electrochemical Sensor
Indications for Use/Intended Use	The FOCUS Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or forearm. Intended to be used by a single patient and should not be shared. Intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. Alternative site testing on the forearm can be used only during steady-state blood glucose conditions. Not intended for the diagnosis of or screening for diabetes, and not intended for use on neonates. FOCUS Blood Glucose Test Strips are used only with FOCUS Meters to quantitatively measure whole blood glucose in fresh, human capillary whole blood taken from the fingertip or forearm. FOCUS Control Solution is for use with FOCUS and FOCUS PRO Meters and Test Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.	The FOCUS PRO Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in venous and arterial whole blood and in fresh capillary whole blood obtained from the fingertip or forearm. Intended for testing outside the body (in vitro diagnostic use) for multi-patient use in a professional healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with sing-use, auto-disabling lancing devices. Alternative site testing on the forearm should be used only during steady-state blood glucose conditions. Not intended for the diagnosis of or screening for diabetes, and not intended for use on neonates. FOCUS PRO Blood Glucose Test Strips are used only with FOCUS PRO Meters for the quantitative measurement of glucose in venous and arterial whole blood and in fresh capillary whole blood taken from the fingertip or forearm. FOCUS Control Solution is for use with FOCUS and FOCUS PRO Meters and Test Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.	The Nova One Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous, arterial and fresh capillary whole blood from the finger and forearm. It is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancets. The Nova One Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates. Alternative site testing on the forearm should be used only during steady-state blood glucose conditions. Nova One Blood Glucose Test Strips are for use with the Nova One Blood Glucose Monitors for quantitatively measuring glucose in venous, arterial and fresh capillary whole blood from the finger and forearm. The Glucose Monitor is calibrated to provide plasma equivalent results to laboratory methods. Nova One Glucose Test Strips are for testing outside the body (in vitro diagnostic use only). The Nova One Blood Glucose Monitor should only be used as directed. They are not intended for the diagnosis of or screening for diabetes, and are not intended for use on newborns.

CHARACTERISTIC	FOCUS Blood Glucose Monitoring System (Self-Monitoring)	FOCUS PRO Blood Glucose Monitoring System (Professional Monitoring)	Predicate Device K122435: Nova One System (Professional Monitoring)
			Nova Max Control Solutions are intended for use with the Nova Max, Nova Max One and Nova One Blood Glucose Monitoring Systems as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Levels 1, 2, 3).
Hematocrit Range (%)	25 - 60	25 - 60	25 - 60
Sample Type	Capillary whole blood from the fingertip, forearm	Venous, arterial whole blood and capillary whole blood from the fingertip, forearm	Venous, arterial whole blood and capillary whole blood from the fingertip, forearm
Sample Size	0.4µL	0.4µL	0.4µL
Glucose Units	mg/dL	mg/dL	mg/dL
Sample Application	Capillary action of test strip	Capillary action of test strip	Capillary action of test strip
Handheld Meter	Yes	Yes	Yes
Meter Data Storage	Up to 400 blood and control solution results	Up to 400 blood and control solution results	Up to 400 blood and control solution results
Analysis Time (seconds)	4	4	4
Insulin Tracking	No	No	No
Power Source	One 3-volt coin cell battery	One 3-volt coin cell battery	One 3-volt coin cell battery
Test Strip Ejector	Yes	Yes	Yes
Test Strip Active Reagent (Enzyme)	Glucose Dehydrogenase - FAD	Glucose Dehydrogenase - FAD	Glucose Dehydrogenase - FAD
Test Strip Calibration Coding	No coding. No user input of calibration code required	No coding. No user input of calibration code required	No coding. No user input of calibration code required
Controls	Liquid, 3 levels	Liquid, 3 levels	Liquid, 3 levels
Automatic Control Detection	Yes, identifies Control sample as Control.	Yes, identifies Control sample as Control	N/A
Lancing Device	Reusable lancing device and sterile lancets	Single use disposable safety lancets (not supplied)	Nova single use disposable safety lancets
Ketone Alert	Yes, when glucose value is above 240 mg/dL. Feature can be turned on/off by the user during set up.	Yes, when glucose value is above 240 mg/dL. Feature can be turned on/off by the user during set up.	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

Nova Biomedical Corporation
c/o Paul W. MacDonald, Ph.D.
200 Prospect St.
WALTHAM MA 02454-9141

Re: K131013
Trade/Device Name: Focus Blood Glucose Monitoring System
Focus Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: October 11, 2013
Received: October 15, 2013

Dear Dr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131013

Device Name: FOCUS Blood Glucose Monitoring System

Indications for Use:

The FOCUS Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or forearm. Intended to be used by a single patient and should not be shared. Intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. Alternative site testing on the forearm can be used only during steady-state blood glucose conditions. Not intended for the diagnosis of or screening for diabetes, and not intended for use on neonates.

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Prescription Use		Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)
_____		X

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Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

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Division Sign-Off
Office of In Vitro Devices and Radiologic Health

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Indications for Use Form

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Prescription Use		Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	X	AND/OR	X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

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